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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,356	09/11/2000	Merrit N. Jacobs	CDS0223	4231

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/658,356

Applicant(s)

JACOBS ET AL.

Examin r

P. Kathryn Bex

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-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1,11 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10,12-14,16 and 17 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The addition of claims 16-18 is acknowledged and has been entered into the record.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "spectrophotometer" in claim 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show a spectrophotometer, reference no. 68, as described in the specification on page 12, lines 1-2. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "38" has been used to designate both "vertical carriage" and "rack", see page 8, lines 6-8. A proposed drawing correction or corrected drawings are required in reply to the

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Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the sample quality measurement tests which includes the measurement for hemoglobin, lipids, bilirubin and biliverdin, does not reasonably provide enablement for one additional test that is also conducted during the step of performing the clinical chemistry tests, further comprising the additional step of: comparing the results of the tests and using the comparison to calibrate the analyzer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification requires that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. Examiner believes that a person of ordinary skill in the art would not conclude a sample quality measurement further comprises the additionally step of comparing the

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test results to calibration values to calibrate the analyzer, since the specification does not mention any collected calibration values or provide working examples.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2-10, 12-14, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a step before step (i) for removing the metering tip from the proboscis in claims 2, 6, 12, which teach crimping and sealing the end of the metering tip. It is unclear as to how measurement steps are subsequently performed on a metering tip which is not sealed since the sample fluid would be lost during and after tip ejection. Moreover, the specification does indicate the crimping and sealing of the tip is critical in the performance of the invention, see page 11, lines 11-12.

10. Claim 7, recite the throughput of the analyzer is increased to a rate greater than a serial method of the operating an analyzer. The term "greater" is a relative term which renders the claim indefinite. The term "greater" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the claim what Applicant considers "greater than" a serial method. Moreover, the specification fails to clarify the subject matter, therefore it is not possible to determine the metes and bounds of the claim as currently recited. Additionally, it is not clear what method steps comprise a "serial method".

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Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 2-10, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs *et al* (USP 5,846,492).

Jacobs *et al* teach a sample quality measurement method within the dispensing tip of a sample-metering device. The method comprising: providing a clinical analyzer with a sample handling apparatus 20 having a plurality of sample containers 19 containing sample; a sample metering apparatus having a proboscis 46, metering tip 48 with aperture at one end, a metering pump 71; a sample processing apparatus 30 having one or more test elements E. The primary analyzer cycle method comprising: attaching a tip to the proboscis to create the metering assembly; moving the metering assembly to immerse the tip in the sample and aspirate sample from the sample container; moving the metering assembly to a dispense the sample liquid on to the test element; the test element is linearly transferred to an incubator (not shown) within which

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it is read or detected at a test station 146 (column 8, lines 10-18). Then, Jacobs *et al* teach performing a secondary quality cycle comprising measurements of the sample through-the-tip 48 at the NIR via spectrophotometer 110 at station 82 (column 5, lines 1-30). Note: the reference teaches the sample liquid can be deposited on the test slide before the through-the-tip analysis (column 8, lines 23-27). Moreover, Jacobs *et al* disclose the spectrophotometric analysis through-the-tip takes 4 seconds compared to the 5 minutes on the slide test element, (column 7, lines 36-38). Therefore, the primary analyzer cycle and the secondary analyzer cycle have steps which occur simultaneously, since the sample liquid can be deposited on the test slide before the through-the-tip analysis and analysis on the test element takes much longer than the through-the-tip analysis. Jacobs *et al* teach the use of calibrators to compare with the test results (Example 1). Jacobs *et al* do not teach the step within the secondary sample quality cycle of removing the metering tip from the proboscis and performing the through-the-tip analysis on the ejected tip.

Corbett *et al* teach a method: introducing a sample into a pipette 13 with a detachable metering tip 21 via an opening in the lower end of the tip ; sealing and crimping the opening; detaching the metering tip from the pipette; and placing the tip into wells 12 and reacting the sample in the tip under controlled temperature conditions (page 3, line 29-page 5, line 6, Figs. 1-2). Such use of a disposable pipette tip as a reaction container for further analysis allows for efficient transfer of the sample and provides time savings and avoids sample contamination (page 3, lines 14-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the apparatus of Jacobs *et al*, the pipette tip of Corbette

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et al in order to allow for efficient transfer of the sample and provide time savings and avoidance of sample contamination (page 3, lines 14-20).

Allowable Subject Matter

14. Claims 12-14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

15. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method comprising: providing a clinical analyzer with a primary analyzer cycle method, involving measurements of a test element, and a secondary quality cycle, involving measurements of the sample through-the-tip via spectrophotometer, which includes the step of aspirating a selected auxiliary volume of the sample from the ejected tip and wherein at least portions of the primary and secondary cycles occur simultaneously.

Conclusion

17. No claims allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

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The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex
Patent Examiner
AU 1743
May 15, 2003

Jill Warden
Jill Warden
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